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Att'y Dkt. No.: US-162

U.S. App. No: 10/790,224

### REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks. No new matter has been added by the foregoing amendments, as full support for these amendments can be found in the examples, the original claims, and paragraph [0054].

### **Priority**

On page 3 of the Office Action, it is noted that the priority document has been received, but that said papers are not in English and no translation has been filed.

Applicants note that a translation of foreign priority documents is not required to satisfy 35 U.S.C. §119, but is only necessary if intervening art is applied to the claims and the translation is required in an Office Action.

### Information Disclosure Statement

On page 3 of the Office Action, Information Disclosure Statement ("IDS") filed March 18, 2005 was objected to, in parts, for allegedly failing to comply with 37 C.F.R. §1.98(a)(2), since the citation of the European Search Report is allegedly improper because the corresponding European application is not referenced, nor was a copy provided. Applicants respectfully disagree.

The March 18<sup>th</sup> IDS included a copy of the European Search Report referenced on the accompanying PTO-1449. Applicant's undersigned representative has reviewed the Image File Wrapper ("IFW") for this application, and has confirmed that a copy of the Search Report is of record; it is listed as "NPL Documents", four (4) pages, on 3/18/2005. To clarify the record, however, a PTO-1449 is provided with a full citation of the European Search Report, including the European application number associated with the Search Report in that corresponding foreign application.

### Objection to the Specification

At page 4 of the Office Action, the Specification was objected to because it allegedly contains a non-descriptive title. Although Applicants do not necessarily agree with this objection, Applicants have amended the title as suggested by the Examiner.

For at least the foregoing reasons, Applicant respectfully submits that the Specification is not objectionable, and therefore respectfully requests withdrawal of the objection thereto.

On page 4 of the Office Action, the disclosure was objected to since the numbering of the examples is allegedly improper. Applicants respectfully disagree with this objection, because there is no requirement in 35 U.S.C., 37 C.F.R., or the M.P.E.P. that examples have to be consecutively numbered. Furthermore, in the instant disclosure, there are not two "example 1", as stated in the Office Action, but a "Reference Example 1" and "Example 1". Applicants assert that these designations are clear and fully in compliance with the requirements for specifications in the M.P.E.P.

For at least the foregoing reasons, Applicant respectfully submits that the Specification is not objectionable, and therefore respectfully requests withdrawal of the objection thereto.

### Objections to the Claims

On page 4 of the Office Action, claims 3 and 4 were objected to for containing non-elected subject matter. The non-elected subject matter has now been deleted without prejudice.

For at least the foregoing reasons, Applicant respectfully submits that the claims are not objectionable, and therefore respectfully requests withdrawal of the objection thereto.

# Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, beginning at page 4, Claims 3 and 4 were rejected under 35 U.S.C. § 112, second paragraph, as reciting subject matters that allegedly are indefinite. Applicant respectfully requests reconsideration of this rejection.

Although applicants do not necessarily agree with the rejection, claim 3 has been amended to recite the mutation point, and claim 4 has been canceled without prejudice. For at least the foregoing reasons, Applicant respectfully submits that Claims 3 and 4 fully comply with 35 U.S.C. § 112, second paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

In the Office Action, beginning at page 6, Claims 8 and 9 were rejected under 35 U.S.C. § 112, second paragraph, as reciting subject matters that allegedly are indefinite. Applicant respectfully requests reconsideration of this rejection.

The limitation of claim 8 has been inserted into claim 1, and the sequence of the arginine repressor has been specified. For at least the foregoing reasons, Applicant respectfully submits that Claims 8 and 9 fully comply with 35 U.S.C. § 112, second paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

# Rejection under 35 U.S.C. § 112, first paragraph

In the Office Action, beginning at page 6, Claims 1-4 and 8-9 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant respectfully requests reconsideration of this rejection.

Claim 1 has been amended to specify that the sequence of the arginine repressor

comprises the protein of SEQ ID NO: 16, or a protein which is 90% or more homologous to the protein of SEQ ID NO: 16. The Office Action states on page 9 that "one of skill in the art would be unable to predict the structure of *all* the other members of these genera by virtue of the instant disclosure" (emphasis by the Examiner). Applicants submit that this is entirely the wrong standard for meeting 35 U.S.C. §112, 1<sup>st</sup> paragraph. Every species which might fall within the claimed genus is not required to be described in the specification, and a person of ordinary skill in the art must only have a reasonable expectation of success of arriving at other members of the genus based upon the prior art and applicant's disclosure. Regarding glutamine synthetase, this protein has a known amino acid sequence, and therefore, it is not required that a specific SEQ ID NO: be present in the claim to satisfy the written description requirement 35 U.S.C. §112, 1<sup>st</sup> paragraph. See *Capon v. Eshhar*, slip op. 03-1480, -1481 (Fed. Cir. 2005). The term "glutamate synthetase" is fully descriptive of the sequence that the term represents, both in light of the specification and the prior art.

For at least the foregoing reasons, Applicant respectfully submits that the Claims fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

In the Office Action, beginning at page 9, Claims 1-4 and 8-9 were rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for *B. lactofermentum* in which activity of the glutamine synthetase described in SEQ ID NO: 20 is enhanced by mutating the adenylylation site at position 405 and in which the gene encoding the arginine repressor described by SEQ ID NO: 15 is disrupted, allegedly does not reasonably provide enablement for genera of coryneform bacteria having L-arginine or L-lysine production ability in which glutamine synthetase activity is enhanced, and in which an argnine repressor is optionally modified encompassed by the scope of the claims. The Examiner apparently feels that undue

experimentation is necessary to practice the claimed methods. Applicant respectfully requests reconsideration of this rejection.

Claim 1 has been amended to specify that the sequence of the arginine repressor comprises a protein which is 90% or more homologous to the protein of SEQ ID NO: 16. Applicants assert that it would of ordinary skill in the art would be enabled to determine arginine repressors which are at least 90% homologous and which do not function normally. A normal function is well-described in the art and in applicant's specification (see paragraphs [0046 through [0056]), and to disable a protein requires less knowledge and skill than attempting to, for example, enhance activity. Therefore, a person of ordinary skill in the art would easily be able to render the arginine repressor as not functionally normally without undue experimentation.

For at least the foregoing reasons, Applicant respectfully submits that Claims 1-4 and 8-9 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

### Rejection under 35 U.S.C. § 101

In the Office Action, beginning at page 12, Claims 1-4 and 8-9 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter.

Applicant respectfully requests reconsideration of this rejection.

Although applicants do not necessarily agree with the basis for the rejection, the claims have been amended to recite that the bacteria is "isolated", as suggested by the Examiner.

For at least the foregoing reasons, Applicant respectfully submits that Claims 1-4 and 8-9 are directed to statutory subject matter, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 101.

# Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 13, Claims 1 was rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by Loos *et al.* as evidenced by U.S. Patent No. 3,708,395. Applicant respectfully requests reconsideration of this rejection.

Claim 1 has been amended to incorporate the limitation of claim 8, which was not rejected over Loos *et al*. For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claim 1 is not anticipated by *Loos et al.*, is therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

## Rejection under 35 U.S.C. § 103(a)

In the Office Action, beginning at page 14, Claims 2-4 were rejected under 35 U.S.C. § 103(a), as reciting subject matters that allegedly are obvious, and therefore allegedly unpatentable, over the disclosure of *Loos et al.* in further view of *Jakoby et al.* and *Arcondeguy et al.* Applicant respectfully requests reconsideration of this rejection.

Claim 1 has been amended to incorporate the limitation of claim 8, which was not rejected over Loos et al., either alone or in hypothetical combination with Jakoby et al. or Arcondeguy et al. Since claims 2-4 depend from claim 1, this subject matter has been incorporated into these claims as well. For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 2-4, each taken as a whole, would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention, are therefore not unpatentable under 35 U.S.C. § 103(a), and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 103(a).

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#### Conclusion

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If the Examiner believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he or she is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the undersigned respectfully requests that our deposit account 50-2821 be charged the requisite fees.

Respectfully submitted,

By:

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